REMARKS

The examiner is asked to reconsider the final rejection because of facts showing that the combination of Brooker and Gilmore does not obviously lead to the subject matter of the pending claims.

In rejection claims 1-3, 5-7, 9-14, 16-21, and 23-25, the office action acknowledges that Brooker does not suggest adjusting a respiratory flow or tidal volume of the inhalation device. The additional citation of Gilmore does not supply this missing feature.

Gilmore does not even relate to an inhalation device, let alone to a device for the controlled inhalation of therapeutic aerosols during breathing manoeuvres as claimed in the present claims. Rather, this reference relates to a ventilator control system and method. Ventilator control systems are provided for totally different purposes, namely to assist patients in breathing, i.e., to ensure that sufficient oxygen is supplied to the lungs of the patient and that the exhaled air is properly removed. To meet this need, ventilator control systems determine the inhalation volume and the breathing frequency of the patient such that sufficient oxygen is supplied to the patient. If these parameters were not determined appropriately, there is the risk that the patient might suffocate.

Merely to serve this purpose, Gilmore et al. suggest an improved ventilator control system for controlling a ventilator pneumatic system using historical patient data stored in a database. The ventilator control system includes a database, which stores a plurality of patient protocols, each patient protocol comprising a set of breath parameters and patient data. A user interface is electrically coupled to the database for selecting a patient protocol. A processor is electrically coupled to the user interface for receiving the selected patient protocol. The processor simultaneously adjusts controls within the ventilator pneumatic system using the selected patient protocol (cf., column 5, lines 23 to 33). Furthermore, Gilmore et al. suggest a method for providing an assisted phase of a breath to a patient connected to such a ventilator pneumatic system. Such a method includes the step of monitoring an accumulated volume of gas inhaled by the patient resulting from the particular spontaneous respiratory muscle activity. More specifically, the monitoring step further comprises measuring a flow of gas inhaled by the patient

resulting from the patient's spontaneous respiratory muscle activity, and integrating the flow to provide the measured accumulated volume (cf., column 5, line 65 to column 6, line 7).

In clear contrast with Gilmore, a patient using the claimed inhalation devices breathes normally and does not need any assistance for inhalation and exhalation of air. Ventilator systems as suggested by Gilmore et al. merely ensure that sufficient air is supplied to the lungs of the patient, whereas with an inhalation device, sufficient air is automatically inhaled by the (healthy) patient. Inhalation devices only assist in transporting an aerosol (in addition to the air) to the lungs of the patient.

In particular, the present invention not only ensures that aerosol is transported to the lungs of the patient in addition to air (i.e., oxygen) but particularly ensures that the appropriate amount of the drug is transported to the lungs, and even ensures that the drug is deposited at the necessary target area in the lungs (i.e., at the bronchi or the alveolus). This is achieved according to the present invention in that the respiratory flow and/or a tidal volume of the inhalation device is adjusted so that an individual aerosol dosage is adjustable on the basis of the predetermined individual patient parameters and/or aerosol parameters. Thus, with the present invention, the desired amount of drug can be transported to the desired treatment area in the lungs. This may also be made dependent on the pharmacokinetics of the used drug.

Although Gilmore suggests controlling the ventilator pneumatic system using a selected patient protocol, Gilmore et al. clearly do not suggest adjusting a respiratory flow and/or a tidal volume of an inhalation device in order to adjust an individual aerosol dosage on the basis of predetermined individual patient parameters and/or aerosol parameters in order to provide a controlled inhalation of a therapeutic aerosol during a breathing manoeuvre.

In other words, the same feature missing from Brooker is likewise missing from Gilmore. Also, an ordinary worker interested in metered inhalation would reject Gilmore's ventilator as cumbersome, expensive, and impractical. A patient who is able to breathe unaided would not be put on a ventilator to accomplish drug inhalation.

For these reasons, even the combination of the teaching of Brooker et al. and Gilmore et al. does not lead the skilled person to an inhalation device according to the present invention. Since Gilmore et al. do not suggest the adjustment of respiratory flow and/or the tidal volume of the inhalation device in order to provide a controlled individualized inhalation of therapeutic aerosols, it would not be obvious in view of Gilmore et al. to provide Brooker et al. with such an individualized adjustment of these parameters.

In rejecting claims 4, 8, 15 and 22, the office action additionally cited Willemot for teaching a keyboard and memory card. These additions do not supply what is missing from any combination of Brooker and Gilmore – namely, adjustment of respiratory flow and/or tidal volume of the inhalation device.

Advantages of the claimed subject matter over the cited art serve as further evidence of unobviousness. These advantages include that the inhalation device according to the present invention is a substantial improvement over conventional inhalation devices. The provision of individual patient parameters and/or aerosol parameters leads to the advantage that these can be provided on a storage medium regardless of the specific inhalation device that is used for inhalation. This allows optimization of the therapy of the patient. Furthermore, this improves safety for the patient because erroneous adjustment of the inhalation device is thus prevented.

Moreover, a clear need for the advantages provided by the claimed subject matter is shown in the enclosed copies of two publications from two journals relevant to the present technical field. These publications (Journal of Aerosol Medicine, Vol. 14, No. 3, 2001, page 388 and The Aerosol Society: Drug Delivery to the Lungs XII, page 23-26) emphasize the advantages that are related to the individualisation of the aerosol inhalation in accordance with the present invention. It is now possible with the claimed invention to provide a pinpointed and more efficient deposition of the drug in the lung, which, in turn, comes along with a decrease of the amount of the necessary drug, which results in a substantial reduction in costs.

In the prior art it is impossible to adjust an inhalation device individually to the specific needs of a specific patient and to an individual drug. This is now possible with an inhalation device according to the present invention. The individualization of the deposition of drugs is becoming more and more important, and the pharmaceutical industry is even now in the process

of developing new strategies for providing individualized drug combinations for each specific patient.

Commercial success of the claimed invention additionally establishes its unobviousness from the cited art. For example, The German company Bayer AG is currently developing a new drug for treatment of a specific type of lung emphysema. Since such patients suffer from severe lung damages, and since the function of the lung is continuously decreasing, it is only possible by means of an individualized inhalation to deposit a sufficient amount of drug in reasonable time into the lung of the patient. The inhalation device according to the present invention is used by Bayer AG for the deposition of this new drug. The corporation agreement between the present applicant and Bayer AG is basically confidential but Bayer AG has already publicly announced that there is cooperation between the present applicants and Bayer AG in this respect.

Reconsideration and withdrawal of the rejections are respectfully requested.

Conclusion

Applicant believes the claims, are patentable over the prior art, and that this case is now in condition for allowance of all claims therein. Such action is thus respectfully requested. If the Examiner disagrees, or believes for any other reason that direct contact with Applicants' attorney would advance the prosecution of the case to finality, he is invited to telephone the undersigned at the number given below.

"Recognizing that Internet communications are not secured, I hereby authorize the PTO to communicate with me concerning any subject matter of this application by electronic mail. I understand that a copy of these communications will be made of record in the application file."

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